

§423.153(d) – Medication Therapy Management Program under Part D

Proposed Rule: The Proposed Part D Rule seeks to significantly expand eligibility standards for Medicare Part D Medication Therapy Management (MTM) programs by redefining the definition of “multiple chronic diseases” to mean *two or more*, reinterpreting “multiple Part D drugs” to mean *two or more*, and reducing the annual cost threshold from \$3,000 to \$620. CMS estimates that these changes would increase MTM eligibility for Part D enrollees from less than 8% in 2011 to 55% in 2015, a seven-fold increase. The preamble to the Proposed Part D Rule attempts to justify an exponential expansion of MTM by stating that enrollment in MTM programs has lagged behind CMS’ expectations during the initial seven years of the Part D benefit. CMS laments the persistently low enrollment in MTM and concludes that the only way to increase participation in Part D MTM programs is to lower eligibility standards dramatically, and thereby expand the pool of potential participants. Further, CMS attributes the failure of MTM programs to meet CMS’ enrollment goals to “variability” in the MTM programs offered by Part D sponsors, and seeks to standardize MTM and reduce, or even eliminate, program variations.

Discussion: PCMA has long supported programs to improve medication therapy. PCMA member companies have led the way by developing and implementing a wide array of innovative programs to improve medication management and health outcomes. MTM is one of many such programs that PCMA member companies have brought to bear on the continuing challenge of improving medication selection and therapeutic adherence. PCMA does not question the importance and need for MTM in the Medicare Part D program when properly targeted and appropriately conducted. However, we have several concerns and strong objections to the significant changes set forth in the Proposed Part D Rule, and question the validity of many of the assumptions articulated in the preamble.

1. Faulty assumptions underlying the Proposed Part D Rule.

- a. CMS appears to assume that low enrollment in MTM is solely due to the actions, or inaction, of PDP sponsors. PCMA vigorously questions that assumption and requests that CMS consider, and factor into its decision making, the numerous diverse elements influencing MTM enrollment. An extremely important element is the role beneficiaries and their physicians play in participation rates and the ultimate success of MTM programs. PCMA member companies report that the change to automatic enrollment of targeted individuals in 2010 had a negligible impact on MTM participation rates, because a persistently high proportion of targeted individuals choose to not participate and instead elected to “opt-out” of the program.

Many individuals, particularly seniors, seem resistant to programs, like MTM, which raise questions about their medication usage and the therapeutic regimen prescribed by their physicians. Targeted individuals who receive a communications from their Part D sponsor, seeking to initiate a dialogue about medication therapy, often consult with their physicians about the merits of such programs. If their physicians are resistant to, or threatened by, such programs and communicate their opposition to

their patients, targeted individuals are much more likely to opt-out. Increasing MTM eligibility will not necessarily increase access or acceptance of beneficiaries to participate in the MTM service offering.

- b. CMS appears to base its assumption of “racial disparities” in meeting the MTM eligibility criteria on two studies by Junling Wang at the University of Tennessee College of Pharmacy. Wang’s 2010 study used Medical Expenditure Panel Survey (MEPS) data from 2004 and 2005, one year prior to implementation of Medicare Part D. MEPS is a federal survey collected annually from representative samples of all non-institutionalized U.S. citizens. Wang tested the hypothesis that non-Hispanic Blacks and Hispanics would have lower likelihood of meeting MTM standards because two of the three eligibility criteria are “based on the use of prescription drugs and health services” and previous literature “reported that minorities use fewer prescription drugs and health services than do whites.” In other words, Wang’s first study is a projection of “what might happen” in Medicare MTM programs under Part D, based on historical population-based utilization data prior to 2006. PCMA believes that historically lower drug utilization among minorities may have been largely due to lack of, or very limited, insurance coverage. To project historical utilization patterns for all age groups onto the Medicare Part D program, based on no actual Part D data, is at best a stretch, and at worst misleading.

The 2012 study by Wang, cited by CMS, again uses non-Medicare MEPS data (although updated to 2007-2008) and applies both the 2008 and the tighter 2010 CMS standards for MTM eligibility. The study’s conclusion that “racial and ethnic disparities in meeting the MTM eligibility criteria may not decrease over time unless the eligibility criteria are changed” appears to be as suspect as the 2010 study findings because neither study is based on actual Medicare Part D beneficiary data. PCMA believes that the Wang studies do not support CMS’ assumptions about racial disparities in Medicare MTM programs, and should not be used to justify significantly lowering the eligibility thresholds as proposed in the Rule.

- c. The preamble also assumes participation in MTM programs is lower for LIS individuals and racial and ethnic minorities than CMS would like because Part D sponsors are not doing enough to reach out to engage with these populations. Typically, these populations are underserved by the health care system, and often live in geographic areas with a dearth of accessible medical care providers. Increasing the participation of these individuals in MTM programs, while laudable, will not remove the high hurdles they face in obtaining meaningful access to comprehensive, quality, and effective medical care. PCMA’s member companies are fully committed to serving these individuals, but CMS needs to have realistic expectations about what can be achieved through MTM interventions alone. MTM is not a panacea for overcoming longstanding and entrenched disparities in American health care.
- d. Instead of simply blaming Part D sponsors for less than desired levels of MTM participation, CMS should consider how incentives might engender more robust Part D sponsor efforts to expand MTM. Hospital and medical care savings from MTM

interventions accrue to Medicare Part A and Part B, not to Part D. PCMA urges CMS to explore ways in which incentives could be provided to Part D sponsors that can demonstrate a link between successful MTM program interventions and corresponding reductions in hospitalizations, use of emergency rooms, or physician visits that lead to Medicare program savings.

2. Research does not support proposed MTM expansion. The August 2013 study by Acumen, “Medication Management in Chronically Ill Populations: Final Report,” (hereafter “Acumen Report”) on which CMS bases many of its assumptions and proposed changes, found that MTM programs changed drug adherence in the first six months of participation, but that “positive effects diminished or reversed by one year after enrollment.” The report states that for the three disease conditions studied (i.e., diabetes, CHF and COPD), MTM programs, on average, increased Part D costs by \$75 to \$181 per patient, and that “comprehensive quantitative evidence of sustained adherence effects have been weak.”

The Acumen Report clearly states that MTM programs which “target high risk, high cost patients with chronic medical conditions” are “an effective tool for improving the health of complex Medicare beneficiaries.” These qualified statements, which appear throughout the report, do not support the proposed expansion of eligibility for MTM programs to all individuals with only two chronic conditions who take two prescription medications. The Acumen Report strongly reinforces the original purpose of MTM in Part D—that MTM is appropriate and effective when applied to a limited subset of Medicare Part D enrollees who are both “high risk” and “high cost.”

Last year, the Agency for Healthcare Research and Quality (AHRQ) conducted a literature review which found that the existing clinical evidence base “is insufficient to address the effectiveness of MTM on most outcomes.” AHRQ calls for the development and application of more rigorous program evaluation designs in order to better evaluate the impact of MTM. The AHRQ findings are highly relevant to the Proposed Part D Rule, but were neither cited nor discussed by CMS.

The recently published findings of a large-scale study of value-based insurance design (VBID) plans challenges commonly held assumptions about the effectiveness of MTM programs. This study, conducted by faculty of Harvard Medical School, found that VBID plans that were more generous with benefits and copay reductions, targeted high-risk patients, offered wellness programs, did *not* offer disease management programs, and made the benefit available only for medication ordered by mail, had a significantly greater impact on medication adherence than plans without these features. The effects were as large as 4-5 percentage points, and were consistent across all the disease states studied. The findings of this study raise questions about the wisdom of the proposed exponential expansion of Medicare Part D MTM programs, and the importance of considering alternative strategies for improving medication adherence and health care outcomes for Medicare beneficiaries.¹³

¹³ N. Choudhry, M. Fischer, B. Smith, G. Brill, C. Girdish, O. Matlin, T. Brennan, J. Avorn, and W. Shrank, “Five Features of Value-Based Insurance Design Plans Were Associated with Higher Rates of Medication Adherence,” Health Affairs 33, No. 3 (2014), pp. 1-9.

3. Adverse effects on beneficiaries from the proposed MTM expansion. Expanding eligibility for MTM programs to approximately 18 million Part D enrollees is a very costly move by CMS with little, if any, evidence that the costs will be offset by corresponding benefits to enrollees or savings to the Medicare program. Several findings noted by the Acumen Report illustrate this:

- a. The effects of MTM interventions on health care costs differ by disease cohort or intervention design.

Of the three diseases Acumen studied, MTM lowered hospital utilization and costs for diabetes and CHF patients receiving comprehensive medication reviews (CMRs), but did not in COPD patients. Also, the Acumen Report only looked at outcomes after one year, and the authors emphasized that improved adherence for many diseases, such as diabetes, would take more than one year to influence health outcomes.

The Acumen Report provides some indication of the incremental increase in Part D costs for the three types of MTM programs it evaluated when it states:

- b. MTM programs on average *increased Part D costs by \$75-\$181 per patient* across all cohorts in the year after enrollment, which may be attributed to improved adherence or other positive drug therapy outcomes.

This estimate does not include administrative and other costs of providing MTM programs, but clearly shows that the proposed expansion of MTM programs to approximately 18 million Medicare Part D beneficiaries would dramatically increase Part D costs.

The Regulatory Impact Analysis conducted by CMS does not even attempt to estimate the overall cost for the proposed MTM expansion and states:

- c. We cannot definitively score this proposal because the portion of the administrative costs attributable to MTM is not a specific line item that can be easily extracted from the bid.

The analysis does estimate that the annual cost of conducting the required CMRs, which are only one component of an MTM program, will be \$111 million based on an assumption of a \$70.91 cost for each CMR.

The high cost of the proposed MTM expansion will have a significant impact on Part D sponsor's bids and likely will be reflected in higher premiums and enrollee cost sharing. Beneficiaries report that the primary factors driving their choice of a Part D plan are premium and cost sharing. PCMA believes that beneficiaries will be very upset about significant increases in their costs for Part D coverage, particularly, if a large portion of those increases is driven by a seven-fold expansion of MTM programs.

4. Expanded eligibility for MTM could hamper beneficiary access to CMRs and lower participation rates. The proposed expansion of MTM eligibility despite currently low levels

of beneficiaries receiving CMRs should raise concerns at CMS about current capacity to perform those reviews. MTM programs encounter major difficulties in identifying and contracting with retail pharmacies in their plan networks that are willing and able to deliver MTM services, including CMRs. PCMA is very concerned about the future availability of adequate numbers of retail pharmacies to provide those services to a greatly expanded pool of targeted individuals. Increasing MTM eligibility without the corresponding capacity to deliver appropriate MTM services actually may *decrease* the participation percentage because the eligible population will be significantly larger. With a bigger MTM population, the quality of the program also may be adversely affected, and this will be reflected in Part D sponsor star ratings. PCMA believes it is both premature and ill-advised for CMS to consider the proposed wholesale expansion of the MTM program. We believe that raising beneficiary expectations about an expanded benefit without having the requisite infrastructure in place to deliver it prior to launch is a recipe for disaster.

5. Proposed expansion undermines the purpose of MTM. The Medicare Modernization Act of 2003 (MMA) requires Part D sponsors to have a MTM program with the goals of identifying drug therapy problems, improving medication use and reducing adverse events for select beneficiaries. §1860D-4(c)(2)(A) of the Social Security Act clearly identifies the eligibility criteria: having multiple chronic conditions, taking multiple Part D medications, and being likely to incur annual costs for overall Part D drugs that exceed a level specified by the Secretary. From the outset, Congress intended, and stakeholders understood, that MTM is a program targeted on beneficiaries who are at risk because of their burden of illness and the probability of medication errors arising from taking multiple prescription drugs, often prescribed by multiple physicians or other health professionals. The likelihood of such individuals experiencing the adverse effects of polypharmacy is high, and MTM programs targeted on such individuals can yield significant benefits. This is what MTM is and was intended to do.

The Proposed Part D Rule “reinterprets” CMS’ previous interpretation of “multiple chronic diseases,” moving the number a plan sponsor may require for targeted enrollment down from three to two. The Proposed Part D Rule “revises” CMS’ previous interpretation of “multiple Part D drugs” down from no more than eight to two. And, the Proposed Part D Rule dramatically lowers the cost threshold from \$3,000 (set in 2010) to \$620. The preamble estimates that these three actions will expand eligibility to 55% of Part D enrollees. PCMA believes that these proposed modifications in the MTM program fundamentally change it from what Congress intended. As proposed, MTM would no longer be targeted on those individuals who are at high risk for adverse outcomes and who incur substantial drug costs for themselves and the program. Instead, MTM would become a very expensive and expanded program that applies to almost all enrollees who utilize the drug benefit.

The preamble recognizes that §3503 of the Affordable Care Act establishes a program under which the Secretary may provide grants or contracts to eligible entities to implement MTM services and provides that such programs shall target individuals who take *four or more* prescribed medications. CMS requests comments on what minimum number of medications is appropriate for MTM targeting.

PCMA strongly believes that most beneficiaries with two chronic conditions who have been prescribed only two medications are poor candidates for MTM. These individuals do not present the complex challenges of managing the medications of individuals with several chronic conditions who take several prescription drugs daily, and are much less likely to be at high risk for medication errors or poor clinical outcomes. Further, such individuals are highly likely to view MTM interventions as intrusive and unnecessary, leading to dissatisfaction with their Part D sponsor. We believe the proposed eligibility expansion would yield a much higher rate of refusals to participate or “opt-outs.” Therefore, PCMA opposes the proposed lowering of the maximum number of chronic diseases from three to two and the maximum number of covered Part D drugs from eight to two.

6. MedPAC Questions about the proposed MTM expansion. In its February 28 letter to CMS, the Medicare Payment Advisory Commission (MedPAC) raises several questions about CMS’ new criteria for MTM eligibility. MedPAC notes that since 2010, CMS has tightened requirements for MTM programs by reducing the number of chronic conditions and Part D covered drugs beneficiaries must have (thereby expanding the potential pool of MTM participants), lowering the estimated annual cost threshold, requiring specific MTM services, and requiring plans to use an opt-out method to enroll eligible plan beneficiaries. Despite these changes, MedPAC points out that enrollment rates remain low, at 8 percent of all Part D enrollees. MedPAC notes that CMS proposes to broaden access by requiring plans to permit beneficiaries with two or more chronic conditions, taking two or more Part D covered drugs, and with a projected annual cost of \$620 to enroll in MTMPs. CMS estimates that 55 percent of Part D enrollees will be eligible for MTM using these criteria.

MedPAC’s responses to CMS’ MTM proposals and its recommendations are quoted below:

Although the Commission supports CMS’ goal of improving medication management, we question whether applying these new criteria to the current program are the most effective way to achieve this goal. As CMS notes, plans are unable to contact many eligible beneficiaries and many beneficiaries refuse the service. In addition, physicians may be reluctant to accept recommendations from drug plans with which they have no direct relationship. Most importantly, the cost of expanding the program to meet the new criteria may be excessive when there is little evidence that Part D MTM programs have been effective for enrolled beneficiaries.

After seven years, it may be time to question whether MTM programs offered through PDPs – without the cooperation and coordination of a beneficiary’s care team – have the capacity to significantly improve beneficiaries’ drug regimens. Plans have little incentive to offer MTM programs. Physicians participating in MedPAC focus groups have said they are not receptive to advice from patients’ insurers, and patients have not been induced to participate. Further, even within MA-PDs, which do have a financial incentive to engage in MTM-like activities, other care management programs or tools may have greater potential to improve outcomes for beneficiaries.

With respect to PDPs, better medication management might be achieved through programs offered by ACOs, medical homes, and other team-based delivery models. Although this type